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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/435,992	HANNA ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *60,65-69,71,72 and 80-99* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *60, 65-69, 71, 72, 80-99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 12/31/03, has been entered.

Claims 60, 65-69, 71-72 and 80-99 are pending

Claims 1-59, 61-64, 70 and 73-79 have been canceled previously.

Claims 60, 65-69, 71-72 and 80-99 are under consideration in the instant application as they read on methods of treating B cell leukemia comprising the administration of anti-CD20 and anti-CD40L antibodies

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Action will be in response to applicant's arguments, filed 12/31/03.
The rejections of record can be found in the previous Office Actions.

3. Upon reconsideration of applicant's amendment and Hariharan affidavit that the submitted Figures 1-4 are described in the instant application as filed, the drawings are entered.

Applicant's provision of Figures 1-4 in conjunction with the Applicant in conjunction with the Hariharan affidavit attests to the fact that Figures 1-4 are supported by the instant specification as filed, particularly page 9, lines 9-18 and the Examples on pages 47-57.

As indicated previously, applicant's Request for Entry of Figures Representing the Results Described in the specification has been DISMISSED by the Office of Petitions, mailed 9/4/02.

4. Claims 68, 82-83, 86-88, 93-99 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

It is apparent that Mab 24-31 and IDEC-C2B8 antibodies are required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the pertinent cell lines / hybridomas which produce these antibodies. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

Applicant's arguments, filed 12/31/03, have been fully considered but are nto found convincing essentially for the reasons of record.

Applicant's amendment, filed 4/22/02, has relied upon the allowance of the humanized anti-CD40L antibody IDEC-131 in a copending application and on the commercial availability of RITUXAN as well as U.S. Patent Nos. 5,776,456 and 5,843,849.

Again, it is noted that certain of these antibodies are claimed in U.S. Patents (e.g. see art rejections below) which would be indicative, but not necessarily mean (see MPEP 2404.01) that the enablement of biological materials under 35 USC, 112, first paragraph, has been satisfied.

Applicant is required to indicate which antibodies are enabled accordingly and to satisfy the deposit of the biological materials for the others accordingly.

Applicant's amendment, filed 12/10/02, which indicated reliance upon U.S. Patent No. 5,843,349 for the enablement of IDEC-C2B8 and upon U.S. Patent No. 6,001,358 for the enablement of Mab24-31 has been acknowledged.

It is noted that the claims recited in U.S. Patent No. 5,843,349 provide for the anti-CD20 antibody produced by transfectoma TCAE 8, which has been accorded ATCC Deposit NO. ATCC 69119 and the murine anti-CD20 antibody secreted by a hybridoma identified by ATCC Deposit No. 11388, which, in turn, appears to provide the appropriate deposit requirements under 35 USC 112, first paragraph for the enablement of IDEC-C2B8.

For clarity, applicant is invited to verify that the recitation of "IDEC-C2B8" refers only to the deposited material recited in the patent claims of U.S. Patent No. 5,843,349.

It is noted that the claims recited in U.S. Patent No. 6,001,358 provide for the certain amino and nucleic acid sequences encoding the variable regions and not the entire immunoglobulin sequence of the anti-CD40L antibody Mab 24-31.

Il is noted that the sequence of an entire immunoglobulin satisfies the biological deposit of said immunoglobulin. Note that satisfaction for the biological deposit of the specific MAb 24-31 antibody requires the disclosure and recitation of its entire amino acid sequence and not based upon partial sequences.

Therefore in contrast to applicant's assertions that there is a question of validity of U.S. Patent No. 6,001,358, applicant's reliance upon U.S. Patent No. 6,001,358 does not appear to provide for the appropriate deposit requirements under 35 USC 112, first paragraph for the enablement of Mab 24-31 in that the U.S. Patent does not provide for the disclosure and recitation of its entire amino acid sequence but rather relies upon partial sequences (e.g. variable light and heavy chain sequences).

While applicant provides the ATCC deposit receipt for the Mab 24-31, applicant is reminded that In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.
Applicant has not provided for the assurances for the deposit of the Mab 24-31.

While applicant relies upon obtaining the 24-31 antibody from Research Diagnostics Inc., it appears that the antibody and not the hybridoma are available from Research Diagnostics Inc. and that the Product Information Sheet indicates: "For in vitro research Use Only. Not for use in or on humans or animals for diagnostics".

Here, it appears that the skilled artisan requires the hybridoma and not just the antibody to generate therapeutic antibodies for the claimed methods. Also, it is not clear whether the Product Information Sheet is indicating a disclaimer or a restriction on the commercially available material.

Applicant's arguments have been fully considered but have not been found persuasive.

5. Claims 66 and 68 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 66 and 68 are indefinite in the recitation of "IDEC-C2B8" and "Mab 24-31" because their characteristics are not known. The use of these "designations" as the sole means of identifying the claimed antibodies renders the claims indefinite because these are merely laboratory designations which do not clearly define the claimed products, since different laboratories may use the same laboratory designations to define completely distinct cell lines .

If the recitation of "IDEC-C2B8" refers only to the deposited material recited in the patented claims of U.S. Patent No. 5,843,439, then this aspect of the rejection will be withdrawn.

Given that U.S. Patent No. 6,001,358 appears to disclose only variable region amino and nucleic acid sequences, then the recitation of "Mab 24-31" does not provide sufficient identification of the entire "Mab 24-31".

Claims 66 and 68 contain the trademark or trade name "IDEC -C2B8". Where a trademark or trade name is used in a claims as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 USC 112, second paragraph, See Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark or the trade name "IDEC-C2B8" is used to identify or describe an antibody, and accordingly, the identification or the description is indefinite. The relationship between a trademark or tradename and the product it identifies may be uncertain and arbitrary. The formula or characteristics of the product may change from time to time and yet it may continue to be sold under the same trademark or tradename.

Applicant is required to indicate whether "IDEC-C2B8" is a trademark or tradename. If "IDEC-C2B8" is not a trademark or a tradename, then this rejection will be withdrawn.

Alternatively, amending the claims to recite the appropriate ATCC Accession Numbers would obviate this rejection

The applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

Applicant arguments have been fully considered but are not found convincing for the reasons set forth herein.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 60, 65-69, 71-72 and 80-99 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kaminski et al. (U.S. Patent No. 6,287,537) AND/OR Anderson et al. (U.S. Patent No. 5,843,439) in view of Smiers et al. (Br. J. Haematol. 93: 125-130, 1996), Schattner et al. (Blood 91: 2689-2697, 1998), Gruss et al. (Leukemia and Lymphoma 24: 393-422, 1997), Renard et al. (Blood 87: 5162-5170, 1996), Black et al. (U.S. Patent No. 6,001,358), Noelle et al. (U.S. Patent No. 5,747,037) in view of standard chemotherapeutic treatments, including combination therapy of leukemias known and practiced by the ordinary artisan at the time the invention was made, as acknowledged on pages 39-40 of the instant specification essentially for the reasons of record set forth in the previous Office Actions.

Claims 60, 65-69, 71-72 and 80-99 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kaminski et al. (U.S. Patent No. 6,287,537) AND/OR Anderson et al. (U.S. Patent No. 5,843,439) in view of Smiers et al. (Br. J. Haematol. 93: 125-130, 1996), Schattner et al. (Blood 91: 2689-2697, 1998), Gruss et al. (Leukemia and Lymphoma 24: 393-422, 1997), Renard et al. (Blood 87: 5162-5170, 1996), Black et al. (U.S. Patent No. 6,001,358), Noelle et al. (U.S. Patent No. 5,747,037) in view of standard chemotherapeutic treatments, including combination therapy of leukemias known and practiced by the ordinary artisan at the time the invention was made, as acknowledged on pages 39-40 of the instant specification essentially for the reasons of record set forth in Paper Nos. 18/24/29
and in further in view of Uhr et al. (U.S. Patent No. 5,686,072) for the reasons of record set forth in the previous Office Action.

Applicant's arguments, filed 12/31/03, have been fully considered but are not convincing essentially for the reasons of record.
Applicant's arguments and the examiner's rebuttal are essentially the same of record.

Applicant request for another non-final Office Action to give applicant a fair opportunity to address the merits of the rejection of record is acknowledged. However, the pending claims as well as the previous claims have been subject to the same or nearly the same rejection since 2001. Therefore, applicant has been given a fair opportunity to address the merits of the rejection.

Reliance on a large number of references in a rejection does not, without more, weight about the obviousness of the claimed invention. In re Gorman 18 USP 2d 1888 (Fed. Cir. 1991). Also, see MPEP 2145, V.

In response to applicant's arguments that there is no suggestion to combine the references, particularly with respect to make the specific combination therapy now claimed, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine 5 USPQ2d 1596 (Fed. Cir 1988) and In re Jones 21 USPQ2d 1941 (Fed. Cir. 1992).

In contrast to applicant's assertions that there was no suggestion or motivation to combine anti-CD20 and anti-CD40L antibodies to treat leukemias , the prior art of record does provides sufficient motivation and expectation of success in combining antagonists of CD40:CD40L interactions in addition to targeting CD20 in the treatment of B cell malignancies, such as leukemia. The strongest rationale for combining reference is a recognition, expressly or implicitly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent that some advantage or expected beneficial result would have been produced by their combination In re Sernaker 17 USPQ 1, 5-6 (Fed. Cir. 1983). Also, see MPEP 2144.

In addition, in response to applicant's argument that there is no suggestion to combine the references, particularly with respect to make the specific combination therapy now claimed; the examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. In re Nomiya, 184 USPQ 607 (CPA 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. In re McLaughlin, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. In re Bozek, 163 USPQ 545 (CCPA 1969).

In response to the combined teachings of Schattner, Gruss and Renard, applicant respond that the combined teaching of the cited references is at best a proposal to try the combination, given that none of the above-noted reference disclose the use of anti-CD40L antibody for B cell lymphoma therapy.

In contrast to applicant's assertions of the rejection is based upon an "obvious-to-try" standard; it is by now well understood that the ultimate conclusion of law that claimed subject matter as a whole would have been obvious under 35 USC 103 may at times properly be drawn from an inference of fact arising from prior art teachings which could be considered an inference that it would be "obvious to try" that which is claimed. In re O'Farrell, 853 F.2d 894, 7 USPQ 2d 1973 (Fed. Cir. 1988); Contour Saws Inc. v. Starrett Co., 444 F. 2d 433, 170 USPQ 433 (Ct.App. 1977); In re Marzocchi, 439 F. 2d 220, 169 USPQ 367 (CCPA 1977); In re Lindell, 385 F. 2d 435, 155 USPQ 521 (CCPA 1967). The evidence of purported unobvious results of record in this application is insufficient to overcome the inference of fact in this case. Therefore the above claims remain rejected under 35 USC 103 for the reasons of record and reiterated herein.

As pointed out in the last Office Action and in contrast to applicant's assertions that there was no suggestion or motivation to combine anti-CD20 and anti-CD40L antibodies to treat leukemias and that the teachings of the secondary references show that leukemia cells show considerable heterogeneity, the following of record is reiterated for applicant's convenience.

Smiers et al. teach that is was known at the time the invention was made that B cell leukemias expressed both CD20 and CD40 and leukemic cells proliferate in response to either CD20 or CD40 activation (see entire document, including Discussion).

Schattner et al. teach that CD40L is expressed on certain chronic lymphocytic leukemias and is important factor in CLL tumor growth as well as an important factor in the generation of pathologic antibody in some patients with CLL (see entire document, including Abstract and Discussion). Schattner et al. also teach that is was known at the time the invention was made that B cell leukemias expressed both CD20 and CD40 (see Abstract).

Gruss et al. teach that CD40 is expressed on B cell leukemias and that the CD40:CD40L pathway, including CD40L-expressing T cells, which are readily detectable around neoplastic B cells, enhance B cell activation and growth (see pages 404-405, B cell Lymphomas and Lymphoproliferative Disorders). It is noted that Gruss et al. teach the therapeutic use of recombinant CD40L rather than CD40L-specific antibodies as inhibitors of malignant B cell growth (page 404, column 1). While Gruss et al. disclose the art known formation of neutralizing anti-mouse antibodies as a limitation of antibody therapy, such limitations have been long addressed by the use of recombinant antibodies such as humanized antibodies, known and practiced in the art for a decade (also, see Noelle et al. and Black et al. herein).

Renard et al. teach autologous $CD4^+$ T cells isolated from leukemia patients were able to induce CD40-dependent proliferation of B cell leukemic blasts (see entire document, including the Abstract). Also, this proliferative response was inhibited by anti-CD40L antibody (see Results).

Therefore, the prior art of Schattner et al., Gruss et al. and Renard et al. taught the importance of CD40L-mediated interactions in B cell leukemia and clinical manifestations. Also as pointed out above, Gruss et al. does teach that CD40:CD40L interactions are par of cellular activation and neoplastic tumor cell growth which would be useful for the therapeutic management of $CD40^+$ tumors (see page 404, column 1).

Therefore, the prior art does provide motivation and expectation of success in combining antagonists of CD40:CD40L interactions in addition to targeting CD20 in the treatment of B cell malignancies, such as leukemia.

As pointed out in the last Office Action, applicant's arguments that it was unknown whether the combination of two unconjugated and non-radiolabeled antibodies would effectively inhibit growth or kill leukemic cells is not found convincing in view of the art and prosecution of record.

As pointed out in the last Office Action, Uhr et al. had been added to provide the teachings that appropriate therapeutic regiments for using antibodies or combination of antibody immunotoxins would be known to those of skill at the time the invention the invention was made in applying anti-B cell antibodies, including combination of anti-B cell antibodies to treat leukemia at the time the invention was made (see entire document, including column 6, paragraph 2 and columns 11-12). Here, Uhr et al. teach the use of combining two different anti-B cell antibodies, including anti-B cell immunotoxins in conjunction with other anti-cancer therapies such as radiotherapy and chemotherapy.

It is noted that the anti-B cell antibodies taught by Uhr et al. affect cell cycle, which, in turn, would be similar to the use of anti-CD20 or anti-CD40L antibodies which affect B cell or B cell leukemia cell proliferation.

Furthermore, as applicant has acknowledged and argued, the claims are not limited to non-radiolabeled antibodies. Applicant has asserted the instant claims encompass both radiolabled and non-radiolabeled anti-CD20 and anti-CD40L antibodies. Therefore, applicant is arguing for limitations not claimed. Clearly, the prior art provides for teaching, motivation and expectation of success in treating leukemia with radiolabeled anti-CD20 and anti-CD40L antibodies, including their combination with known chemotherapeutic treatments for leukemia by the ordinary artisan at the time the invention was made.

One of ordinary skill in the art at the time the invention was made would have been motivated to select radiolabeled CD20-specific antibodies, non-radiolabeled CD40L-specific antibodies and standard chemotherapeutic to treat B cell leukemia at the time the invention was made, given the teachings above. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments are not found persuasive.

8. Claims 60, 65-69, 71-72 and 80-99 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over pending claims of copending applications USSN 09/772,938 . Given the election in the instant case, the conflicting claims may or may not be identical, depending upon the invention(s) elected in these copending applications. The claims are not patentably distinct from each other because they appear to read on the same or nearly the same reagents to treat the same or nearly the same leukemias and lymphomas.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Again, applicant's amendment requests that this provisional rejection be held in abeyance until allowable subject matter is indicated.

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phillip Gambel, PhD.
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May 10, 2004